

50454-56101USCIP3**09/470,603**

APPLICANT

Eugenio Cefali

FILING DATE

31 October 1997

GROUP

1615U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|----------------------|--------------------|------|------|-------|----------|-------------------------------|
| | | | | | | |

FOREIGN PATENT DOCUMENTS

| DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES/NO/ OR ABSTRACT |
|--------------------|------|---------|-------|----------|---------------------------------------|
| | | | | | |

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|---|---|
| 1 | Expert Report of Cheryl D. Blume, Ph.D. (January 27, 2004) - Subject to Protective Order |
| 2 | Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version] - Subject to Protective Order |
| 3 | Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004) - Subject to Protective Order |
| 4 | Expert Report of Dr. Sergio Fazio Regarding U.S. Patent No. 6,676,967 (August 17, 2004) - Subject to Protective Order |
| 5 | Expert Report of Don W. Martens (February 6, 2004) [Redacted Version] - Subject to Protective Order |
| 6 | Expert Report of Don W. Martens Regarding U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version] - Subject to Protective Order |
| 7 | Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version] - Subject to Protective Order |
| 8 | Expert Report of Dr. Joseph R. Robinson Regarding U.S. Patent No. 6,676,967 (August 18, 2004) - Subject to Protective Order |
| 9 | Rebuttal Expert Report of Thomas S. Foster, Pharm.D. (April 2, 2004) - Subject to Protective Order |

| | |
|----|---|
| 10 | Rebuttal Expert Report of Thomas S. Foster, Pharm.D. Regarding The '967 Patent (October 4, 2004) - Subject to Protective Order |
| 11 | Rebuttal Expert Report of James W. McGinity, Ph.D. (April 2, 2004) - Subject to Protective Order |
| 12 | Supplemental Rebuttal Expert Report of James W. McGinity, Ph.D. (August 18, 2004) - Subject to Protective Order |
| 13 | Rebuttal Expert Report of James W. McGinity, Ph.D. Regarding The '967 Patent (September 30, 2004) - Subject to Protective Order |
| 14 | Expert Report of Mark E. McGovern, M.D. (February 6, 2004) - Subject to Protective Order |
| 15 | Expert Report of Mark E. McGovern, M.D. (August 20, 2004) - Subject to Protective Order |
| 16 | Expert Report of Frank M. Sacks, M.D. (April 2, 2004) - Subject to Protective Order |
| 17 | Expert Report of Frank M. Sacks, M.D. (August 20, 2004) - Subject to Protective Order |
| 18 | Rebuttal Expert Report of Mary Ann Tucker, Esq. (April 2, 2004) - Subject to Protective Order |
| 19 | Rebuttal Expert Report of Mary Ann Tucker, Esq. Regarding The '967 Patent (October 1, 2004) - Subject to Protective Order |
| 20 | Carl J. Lavie, et al., <i>Marked Benefit with Sustained-Release Niacin Therapy in Patients with Isolated@ Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease</i>, Am. J. Cardiol. 1992;69:1083-1085 |
| 21 | Excerpts from the 1993, 2000, and 2002 editions of the Physician's Desk Reference |
| 22 | <i>Niacin: Double-edged Sword for Lowering Cholesterol</i>, Tufts University Diet & Nutritional Letter (Tufts Univ., Boston, MA), August 1994, Vol. 12, issue 6 |
| 23 | Larsen, ML and Illingworth, DR, <i>Drug Treatment of Dyslipoproteinemia</i>, Med Clin N Am., 78:225-245 (1994) |
| 24 | Lavie, Letter to Editor, JAMA 1994; 272:513-515 |

| | | |
|--|----|--|
| | 25 | Keenan, Letter to Editor, JAMA 1994; 272:513-515 |
| | 26 | Shields & Beckmann, Letter to Editor, JAMA 1994; 272:513-515 |
| | 27 | Thomas N. Tozer, Clinical Pharmacokinetics Concepts and Applications (3d ed. 1995) at Chapter 9, p. 120 |
| | 28 | Excerpts from the United States Pharmacopeia (1995) |
| | 29 | Morgan & Capuzzi Abstract, <i>Safe and Effective Treatment of Dyslipidemia by Niaspan, a New Sustained-Release Niacin</i> , Clinical Pharmacology & Therapeutics (February 1996) |
| | 30 | Morgan & Capuzzi Article, <i>Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial</i> , J. Cardiovasc. Pharmacol. Therapeut. 1(3):195-202 (July 1996) |
| | 31 | Capuzzi DM, et al., <i>Efficacy and Safety of An Extended-Release Niacin (Niaspan): A Long-Term Study</i> , Am J Cardiol. 1998;82:74U-81U |
| | 32 | Guyton JR, <i>Advances in Dyslipidemia: Discussion Session II</i> , Am J Cardiol, 1998: 82(12A): 85U-86U |
| | 33 | Knopp RH, et al., <i>Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Given Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia</i> , Metabolism 47:1097-1104 (1998) |
| | 34 | American Diabetes Association: <i>Management of Dyslipidemia in Adults with Diabetes</i> , Diabetes Care 21:179-182, 1998 |
| | 35 | Elam MB, et al., <i>Effect of Niacin on Lipid and Lipoprotein Levels and Glycemic Control in Patients With Diabetes and Peripheral Arterial Disease</i> , JAMA: 2000; 284:1263-1270 |
| | 36 | Kesala R, et al., <i>Niacin (N) vs. Niaspan (NS) Treatment of the Atherogenic Lipid Profile (ALP; Small, Dense LDL, HDL2, HDLc and Triglycerides) and Lp(a) in Diabetic Patients (DP)</i> , Diabetes 49 (suppl. 1): A268 at 1114-P (June 2000) |
| | 37 | 2001 NCEP Report at VI-11, Table VI.2-3 |
| | 38 | Wang, W. et al., <i>Effect of Nicotinic Acid Administration on Hepatic Very Low Density Lipoprotein-Triglyceride Production</i> , Am J Physiol Endocrinol Metab., 280:E540-E547 (2001) |

| | | |
|----------|----|---|
| | 39 | Smith SC, et al., <i>AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 Update</i>. AHA/ACC Scientific Statement, 1577-79 |
| | 40 | Tavintharan S and Kashyap M, <i>The Benefits of Niacin in Atherosclerosis</i>, Curr Athero. Reports 2001; 3:74-82 |
| | 41 | Meadows M., <i>Serious Liver Injury: Leading Reason for Drug Removals, Restrictions</i>, FDA Consumer Magazine, May-June 2001; http://www.fda.gov/fdac/features/2001/301_liver.html |
| | 42 | Grundy SM, et al., <i>Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated with Type 2 Diabetes</i>. Arch Intern Med. 2002; 162: 1568-1576 |
| | 43 | American Diabetes Association: <i>Management of Dyslipidemia in Adults with Diabetes</i>, Diabetes Care 25:S74-S77, 2002 |
| | 44 | Pan J, et al., <i>Niacin Treatment of the Atherogenic Lipid Profile and Lp(a) in Diabetes</i>, Diabetes, Obesity and Metabolism 4:255-261 (2002) |
| | 45 | Pan J, et al., <i>Extended-Release Niacin Treatment of the Atherogenic Lipid Profile and Lipoprotein(a) in Diabetes</i>, Metabolism 51:1120-1127 (2002) |
| | 46 | Meyers CD, et al., <i>Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia</i>, Ann Intern Med. 2003; 139:996-1002 |
| | 47 | CDER <i>Guidance for Industry, Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations</i> (March 2003) |
| | 48 | American Diabetes Association: <i>Dyslipidemia Management in Adults with Diabetes</i>, Diabetes Care 27:S68-S71, 2004 |
| | 49 | Sample Kos Clinical Trial Medical Consent Form - Subject to Protective Order |
| | 50 | Sample Kos Clinical Trial Investigator's Statement - Subject to Protective Order |
| EXAMINER | | DATE CONSIDERED |